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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,088	04/01/2005	Chung K. Chu	G25-080US Nat	7531

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EXAMINER	
OLSON, ERIC	
ART UNIT	**PAPER NUMBER**
1623	
MAIL DATE	**DELIVERY MODE**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,088	CHU ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 45-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted June 11, 2007 wherein claims 12, 23, 24, 30, 45, and 47 are amended. This application is a national stage application of PCT/US03/39029, filed December 8, 2003, which claims benefit of provisional application 60/431812, filed December 9, 2002.

Claims 1-40 and 45-47 are pending in this application.

Claims 1-40 and 45-47 as amended are examined on the merits herein.

Applicant's amendment, submitted June 11, 2007, with respect to the objection to claim 47 for depending from a cancelled base claim, has been fully considered and found to be persuasive to remove the rejection as the claim has been amended to depend from currently pending claim 23. Therefore the objection is withdrawn.

Applicant's amendment, submitted June 11, 2007, with respect to the rejection of claim 47 under 35 USC 101 for reciting a use without any steps involved in the method or process, has been fully considered and found to be persuasive to remove the rejection as the claim has been amended to recite a pharmaceutical composition instead of a use. Therefore the rejection is withdrawn.

Applicant's amendment, submitted June 11, 2007, with respect to the rejection of claim 47 under 35 USC 112, second paragraph for reciting a use without any steps involved in the method or process, has been fully considered and found to be

persuasive to remove the rejection as the claim has been amended to recite a pharmaceutical composition instead of a use. Therefore the rejection is withdrawn.

Applicant's argument, submitted June 11, 2007, with respect to the rejection of claims 1, 8-12, 19-22, 30, and 37-40 under 35 USC 102(b), for being anticipated by Liotta et al., has been fully considered and found to be persuasive to remove the rejection as the claims require that the HIV strain be drug-resistant. Therefore the rejection is withdrawn.

The following rejections of record in the previous office action are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-29, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Belleau et al. (US patent 7199202, cited in PTO-1449) Belleau et al. discloses a variety of compounds including cis- and trans- 2-acetoxymethyl-4-(thymin-1'-yl) 1,3-dioxolane, and cis- and trans- 2-hydroxymethyl-4-(thymin-1'-yl)-1,3-dioxolane, all of

which are compounds of the formula disclosed in instant claim 1. (column 10, lines 59-64) These compounds are useful in therapeutic methods and pharmaceutical compositions for the treatment and prophylaxis of retroviral infections, particularly HIV. (column 11, lines 33-67, column 12, lines 44-67) The compounds may be formulated and administered in combination with other anti-HIV agents of various types, including the reverse transcriptase inhibitors dideoxycytidine and dideoxyinosine. (column 14, lines 28-63) Thus the claimed invention is anticipated by Belleau et al.

Response to Argument: Applicant's arguments, submitted June 11, 2007, with respect to the above ground of rejection have been fully considered but not found to be persuasive to remove the rejection. Applicant argues that Belleau et al. does not disclose the treatment of a drug-resistant form of HIV using the disclosed compounds. However, as regards the compositions of claims 23-29 and 47, usefulness for treating drug-resistant HIV is an inherent property of the claimed composition and does not render these compositions patentable over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Therefore the rejection is deemed proper and made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 8-16, 19-22, 30-34, 37-40, and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liotta et al. (US patent 5852027, cited in PTO-1449) Liotta et al. discloses methods for prevention and treatment of viral infections, including HIV infections, comprising administering an antiviral 1,3-dioxolane nucleoside, and pharmaceutical compositions comprising such nucleosides. (column 13, line 33 – column 14, line 33) specific pharmaceutically acceptable compounds of the invention of Liotta et al. include compounds identical to those of instant claim 1, including wherein R1 is hydrogen, alkyl, or acyl. Additionally, 2'-deoxy-3'-oxothymidine (R1=H) is shown to inhibit HIV activity *in vitro*. (figure 2, compound 11, also shown TBDMS-protected as compound 6, column 17, lines 33-45) Liotta et al. does not explicitly disclose a method of treating specifically AZT and 3TC resistant strains of HIV.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods and compositions of Liotta et al. to treat HIV infections resistant to 3TC and AZT. One of ordinary skill in the art would have been motivated to practice the invention in this manner because the invention of Liotta et al. is disclosed to be useful for the treatment and prevention of HIV infections generally. One of ordinary skill in the art would have reasonably expected success because it is well-known, routine, and commonplace in the treatment of drug-resistant infections to substitute a different drug to which the infectious agent is not resistant.

Note that, although claims 1 and 30 were not rejected under 35 USC 103 over Liotta et al. in the first office action, the rejections of dependent claims 2-4 and 31-34 clearly also apply to the base claims as well.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted June 11, 2007, with respect to the above ground of rejection have been fully considered but not found to be persuasive to remove the rejection. Applicant argues that the prior art does not particularly point out that the claimed compounds are particularly effective against strains of HIV that are resistant to 3TC and/or AZT, and that this property could not be discovered without taking the time to test the compound against a number of drug-resistant HIV strains, and that furthermore Liotta et al. does not disclose any activity against drug-resistant strains of HIV.

With respect to the lack of a specific disclosure of drug-resistant HIV in the reference, it is very common and well-known in the medical and pharmaceutical arts that drug-resistant conditions displaying resistance to one drug should be treated by switching to a different drug. This is the case not only for HIV but for other disorders such as tuberculosis or cancer that display drug-resistant phenotypes. The fact that a particular drug can treat a condition that is resistant to other, structurally distinct drugs is not surprising in the least and would be immediately grasped by anyone of ordinary skill in the art.

With respect to the specific agents 3TC and AZT, applying the therapy of Liotta et al. to these particular drug-resistant strains represents only routine, predictable

experimentation. One of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. Putting these embodiments into practice would require only simple *in vitro* experimentation that is utterly routine and well within the level of skill in the art. This modification is the result not of innovation but of ordinary skill and common sense.

Therefore the rejection is deemed proper and made **FINAL**.

Claims 1-22, 30-40, and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Belleau et al. (US patent 7199202, cited in PTO-1449) The disclosure of Belleau et al. is discussed above. Belleau et al. does not explicitly disclose a method of treating specifically AZT and 3TC resistant strains of HIV or the various strains recited in instant claims 45-47.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the methods and compositions of Belleau et al. to treat HIV infections resistant to 3TC and AZT and the various strains recited in instant claims 45-47. One of ordinary skill in the art would have been motivated to practice the invention in this manner because the invention of Belleau et al. is disclosed to be useful for the treatment and prevention of HIV infections generally. One of ordinary skill in the art would have reasonably expected success because it is well-known, routine and commonplace in the treatment of drug-resistant infections to substitute a different drug to which the infectious agent is not resistant.

Note that, although claims 1 and 30 were not rejected under 35 USC 103 over Belleau et al. in the first office action, the rejections of dependent claims 2-4 and 31-34 clearly also apply to the base claims as well.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted June 11, 2007, with respect to the above ground of rejection have been fully considered but not found to be persuasive to remove the rejection. Applicant argues that the prior art does not particularly point out that the claimed compounds are particularly effective against strains of HIV that are resistant to 3TC and/or AZT, and that this property could not be discovered without taking the time to test the compound against a number of drug-resistant HIV strains, and that furthermore Belleau et al. does not disclose any activity against drug-resistant strains of HIV.

With respect to the lack of a specific disclosure of drug-resistant HIV in the reference, it is very common and well-known in the medical and pharmaceutical arts that drug-resistant conditions displaying resistance to one drug should be treated by switching to a different drug. This is the case not only for HIV but for other disorders such as tuberculosis or cancer that display drug-resistant phenotypes. The fact that a particular drug can treat a condition that is resistant to other, structurally distinct drugs is not surprising in the least and would be immediately grasped by anyone of ordinary skill in the art.

With respect to the specific agents 3TC and AZT, applying the therapy of Belleau et al. to these particular drug-resistant strains represents only routine, predictable

experimentation. One of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. Putting these embodiments into practice would require only simple *in vitro* experimentation that is utterly routine and well within the level of skill in the art. This modification is the result not of innovation but of ordinary skill and common sense.

Therefore the rejection is deemed proper and made **FINAL**.

Claims 5-7, 17, 18, 23-29, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liotta et al. (US patent 5852027, cited in PTO-1449) in view of the Merck Manual of Diagnosis and Therapy, seventeenth edition. (Reference included with PTO-892m herein referred to as Merck) The disclosure of Liotta is discussed above. Liotta et al. does not disclose a method or composition additionally comprising a second HIV drug as disclosed in instant claims 5-7, 17, 18, 23-29, 35, and 36.

Merck discloses that patients with HIV be treated with combination therapy of two or more HIV drugs, including two nucleosides. (p. 1321, left column, paragraph 5 – right column paragraph 4) Merck also discloses that 3TC, ddI, ddC, and abacavir are nucleoside anti-HIV drugs, and additionally that NVP and DLV are non-nucleoside anti-HIV drugs. (p. 1322, table 163-3)

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the methods and compositions of Liotta et al. in combination with an additional anti-HIV drug, particularly a second nucleoside such as 3TC, ddI, ddC, or abacavir. One of ordinary skill in the art at the time of the invention would have been

motivated to combine the references in this manner because Merck discloses that it is standard practice to administer two nucleosides in combination. One of ordinary skill in the art would have reasonably expected success because both the compounds of Liotta et al. and those disclosed by Merck are seen to be useful for the same purpose, that is the treatment of HIV. It has been held that it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose in order to practice a third composition for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted June 11, 2007, with respect to the above ground of rejection have been fully considered but not found to be persuasive to remove the rejection. Applicant argues that the prior art does not particularly point out that the claimed compounds are particularly effective against strains of HIV that are resistant to 3TC and/or AZT, and that this property could not be discovered without taking the time to test the compound against a number of drug-resistant HIV strains, and that furthermore Liotta et al. does not disclose any activity against drug-resistant strains of HIV.

With respect to the lack of a specific disclosure of drug-resistant HIV in the reference, it is very common and well-known in the medical and pharmaceutical arts that drug-resistant conditions displaying resistance to one drug should be treated by switching to a different drug. This is the case not only for HIV but for other disorders

such as tuberculosis or cancer that display drug-resistant phenotypes. The fact that a particular drug can treat a condition that is resistant to other, structurally distinct drugs is not surprising in the least and would be immediately grasped by anyone of ordinary skill in the art.

With respect to the specific agents 3TC and AZT, applying the therapy of Liotta et al. to these particular drug-resistant strains represents only routine, predictable experimentation. One of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. Putting these embodiments into practice would require only simple *in vitro* experimentation that is utterly routine and well within the level of skill in the art. This modification is the result not of innovation but of ordinary skill and common sense.

Therefore the rejection is deemed proper and made **FINAL.**

Conclusion

No claims are allowed in this application. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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